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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,103	10/16/2006	John C. Bell	18041B-PCTUS	1653

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Legal Department
930 Clopper Road
Gaithersburg, MD 20878

EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
08/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,103	BELL ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6,8 and 10-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3-6,8,10-15 and 20* is/are allowed.

6)☒ Claim(s) *16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/23/09 has been entered.

Response to Amendment

The 1.131 declaration filed on 7/23/09 under 37 CFR 1.131 is sufficient to overcome the Whitt et al (US 2005/0260601) reference.

The objection to claim 4 is withdrawn in view of the amendment to the claim.

Election/Restrictions

Claims 3-6, 8, 10-15, 20 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 16-19, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 10/26/2007 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim

presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112

Claims 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16-19 provide for the use of mutant VSV, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 16-19 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing an immune response by

administering the vaccine vector of claim 11, or an oncolytic treatment method comprising administering the oncolytic agent of claim 13, or a method of expressing a heterologous nucleic acid by infecting a host cell with the VSV of claim 10, does not reasonably provide enablement for the full scope of methods claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

There are several different issues involved in this rejection.

Claims 17-18 involve "treatment of a disease or disorder that can be alleviated by cytokine release," more specifically cancer, bacterial infection, viral infection, and fungal infection. The specification provides little guidance as to appropriate patients to treat, or how to administer the virus in order to obtain therapeutic benefit from the cytokine release. A search of the art involving cytokine release indicates that cytokine release is commonly seen as an adverse reaction, see for example the review by Descotes et al (Expert Opinion on Drug Metabolism and Toxicology 4:1537-1549, 2008, not prior art). Therefore, one skilled in the art would need substantial guidance on how to use cytokine release in order to alleviate a disease or disorder. Absent such guidance in the specification, it is concluded that undue experimentation would be required to enable the treatment method of claims 17-18.

Claim 19 involves delivery of a heterologous nucleic acid "to a subject in need thereof,: i.e., gene therapy. The review by Barber (Viral Immunology 17(4): 516-527, 2004) is cited as illustrating the state of the art of VSV vector use at approximately the time of the invention. Barber indicates routine knowledge of vaccine and oncolytic

applications, and the specification provides substantial guidance and working examples involving oncolysis in mouse tumor models. However, Barber does not indicate routine knowledge for the full spectrum of gene therapy applications, such as treatment of genetic diseases. Considering the limited guidance in the specification and the state of the art, it is concluded that undue experimentation would be required to enable the full scope of the treatment method of claim 19.

In regard to claim 16, the claim appears to be broadly drawn to a method involving addition of the claimed VSV as an additive to a pharmaceutical preparation of viruses, for the purpose of protecting (a patient?) against virulent revertants of the pharmaceutical virus. The specification teaches that co-administering WT VSV with >1,000-fold excess of mutant VSV does prevent the normal morbidity and mortality associated with WT VSV, see figure 1C. Although the mutant VSV was a point mutant rather than the claimed deletion mutant, the biological properties of the two should be similar. The specification speculates that cells infected with the mutant VSV induce interferons and other cytokines, which protect neighboring cells from infection or spread of revertant virus. However, the specification does not teach how to obtain the desired results when the mutant VSV is "an additive" to a population of viruses, not in a thousand-fold excess. Nor does the specification teach how to obtain the desired benefit for an unrelated virus. Considering the limited guidance in the specification, the limited scope of the working examples, and the unpredictability of the art, it is concluded that undue experimentation would be required to practice the full scope of this invention.

Allowable Subject Matter

Claims 3-6, 8, 10-15, 20 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

8/17/09